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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/007,268	01/14/1998	JOHN A. LOWE, III	PC7981C	4701

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PFIZER INC  
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NEW YORK, NY 10017-5612

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/007,268	<b>Applicant(s)</b> LOWE, ET AL.	
	<b>Examiner</b> Cybille Delacroix-Muirheid	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33,36,37 and 39-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,36 and 39-62 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

The following is responsive to Applicant's amendment received Dec. 24, 2003.

Claims 1-32, 34-35, 38 are cancelled. No new claims are added. Claims 33, 36-37, 39-62 are currently pending.

The previous rejection of claim 38 under 35 USC 112, paragraph 1 (written description), set forth at pages 2-3 of the office action mailed August 21, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 33, 36, 39-57, 58, 59, 60-62 under 35 USC 112, paragraph 1 (written description) set forth at pages 3-4 of the office action mailed August 21, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of claims 33, 36, 39-62 under 35 USC 112, paragraph 1 (enablement) set forth at pages 4-7 of the office action mailed Aug. 21, 2003 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Aug. 21, 2003 with the following additional comment:

Applicant states that the rejection has been overcome by canceling the term "preventing" from the claims. However, such an amendment does not fully address the enablement rejection. As stated in the office action mailed Aug. 21, 2003, Applicant's specification does not appear to provide guidance for the treatment and prevention of all the claimed diseases and conditions. The specification provides no guidance to enable

one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous disorders. Applicant's specification does not set forth a representative number of examples of diseases or disorders, which the claimed compounds would be capable of treating or preventing.

Furthermore, there are no working examples, in vivo or in vitro, in the specification relating to the treatment or prevention of any of the claimed diseases or disorders. The specification provides examples directed to preparing the compounds encompassed by the claims. The only "working example" disclosed is at pages 34-35, where Applicant describes a radioligand binding procedure to study the ability of the claimed compounds to inhibit the binding of Substance P to receptor sites in bovine caudate tissue. Then at page 35, lines 11-25, Applicant describes that the neuroleptic activity of the compounds may be carried out in guinea pigs by following the disclosed procedural steps.

Thus, since (1) prevention of neuropathological diseases (Alzheimer's disease) as well as some of the other disorders claimed by Applicant has not been achieved and thus recognized in the art, and (2) since the only working example in Applicant's specification is a radioligand assay to study the inhibitory activity of the claimed compounds against Substance P, and (3) since compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, especially for each of the claimed disorders, one of ordinary skill in the art would be burdened with undue experimentation to determine the pharmacological parameters

i.e. dosage, etc. necessary to enable one of ordinary skill in the art to actually prevent and/or treat the numerous diseases claimed by Applicant as well as to prevent the occurrence of neuropathological disorders, autoimmune disorders, etc.

Therefore, the rejection is respectfully maintained.

Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Claims 33, 36, 39-62 stand rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

May 3, 2004



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